Field Name	Field Description
Prior Authorization Group Description	**Complement Inhibitors**
Drugs	**Soliris (eculizumab), Ultomiris (ravulizumab), Empaveli (pegcetacoplan)**
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, the Drug Package Insert, and/or per the standard of care guidelines
Exclusion Criteria	N/A
Required Medical Information	See "other criteria"
Age Restrictions	N/A
Prescriber Restrictions	Prescriber must be a hematologist, nephrologist, neurologist, oncologist, or other appropriate specialist.
Coverage Duration	If the criteria are met, the initial request will be approved for up to 3 month duration; reauthorization requests will be approved for up to 6 months. If the criteria are not met, the request will be referred to a clinical reviewer for medical necessity review.
Other Criteria	****Drug is being requested through the member's medical benefit**** **<u>Initial Authorization:</u>** • The request is age appropriate according to FDA approved package labeling or nationally recognized compendia; **AND** • The request is for a dose that is FDA approved or in nationally recognized compendia in accordance with the patient's diagnosis, age and concomitant medical conditions; **AND** • Documentation of vaccination against meningococcal disease or a documented medical reason why the patient cannot receive vaccination or vaccination needs to be delayed; **AND** • Antimicrobial prophylaxis with oral antibiotics (penicillin, or macrolides if penicillin-allergic) for two weeks will be administered if the meningococcal vaccine is administered less than two weeks before starting therapy or a documented medical reason why the patient cannot receive oral antibiotic prophylaxis. **Paroxysmal Nocturnal Hemoglobinuria (PNH):** • Documentation of diagnosis by high sensitivity flow cytometry • Hemoglobin (Hgb) < 10.5 g/dL

	• If the request is for Empaveli (pegcetacoplan), documented trial and failure of, contraindication to, or medical reason for not using Soliris (eculizumab) or Ultomiris (ravulizumab) **Generalized Myasthenia Gravis (gMG):** • The request is for Soliris (eculizumab) **or Ultomiris (ravulizumab)** • Patient has a positive serologic test for anti-AChR antibodies; **AND** • Patient has a Myasthenia Gravis Foundation of America (MGFA) clinical classification of class II, III or IV at initiation of therapy; **AND** • Patient has a Myasthenia Gravis-specific Activities of Daily Living scale (MG-ADL) total score ≥ 6 at initiation of therapy; **AND** • One of the following: o Failed treatment over a total of 1 year or more with 2 or more immunosuppressive therapies (ISTs) either in combination or as monotherapy; **OR** o Failed at least 1 IST and required chronic plasmapheresis or plasma exchange or intravenous immunoglobulin; **OR** o Has a documented history of contraindications or intolerance to ISTs **Neuromyelitis Optica Spectrum Disorder (NMOSD)** • Refer to the "Neuromyelitis Optica Spectrum Disorder (NMOSD) Agents" policy **Atypical Hemolytic Uremic Syndrome (aHUS)/Complement-Mediated HUS)** • Documentation of confirmed diagnosis as evidenced by complement genotyping and complement antibodies; **OR** • Provider attestation treatment is being used empirically and delay in therapy will lead to unacceptable risk to the patient **Re-Authorization:** • Provider has submitted documentation of clinical response to therapy (e.g., reduction in disease severity, improvement in quality of life scores, reduced need for blood transfusions); **AND** • The request is for ~~an FDA approved dose~~ **a dose that is FDA approved or in nationally recognized compendia in accordance with the patient's diagnosis, age, and**

Revision/Review Date ~~7/2021~~**7/2022**	**concomitant medical condition**; **AND** • If the request is for aHUS/Complement Mediated HUS ○ Documentation of confirmed diagnosis as evidenced by complement genotyping and complement antibodies **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**